SUPPORT FOR THE AMENDMENT

Support for the amendment to claim 1 is found in claims 4 and 21 as originally presented and on page 18, lines 5. No new matter would be added to this application by entry of this amendment.

Upon entry of this amendment claims 1-3, 5-12, 14 and 16-21 will now be active in this application, with claims 1-3, 5-8, 10-12, 14 and 16-21 being under active consideration.

REQUEST FOR RECONSIDERATION

The claimed invention is directed to a hair cosmetic composition.

Hair quality can be reduced as a result of physical and chemical actions (drying, brushing, shampooing, dyeing, bleaching) and as well as by aging. Hair conditioning composition containing ceramide or glycosylceramide have been proposed but experience difficulty in formulation and effectiveness due to a high melting point and ease of crystallization of the conditioning agent. Accordingly an improved hair cosmetic composition based on an amphipathic amide lipid is sought.

The claimed invention addresses this problem by providing a hair cosmetic composition comprising an amphipathic amide lipid and an ethylene glycol monofatty acid ester or ethylene glycol difatty acid ester containing in said fatty acid composition thereof, from 65 to 90 wt. % of stearic acid and mixtures thereof. Applicants have discovered that this combination of components, **in a ratio of from 1:1 to 1:30** to provide a pearlescent and stable dispersion of components in which adsorption to the hair of the amphipathic amide lipid is promoted. Such a composition is nowhere disclosed or suggested in the cited references of record.

The rejection of claims 1-8, 10-12, 14 and 16-21 under 35 U.S.C. 103(a) over Hoshina et al. EP 1,166,766 in view of Uchiyama et al. U.S. 5,876,705 is respectfully traversed.

The cited combination fails to suggest the combination of amphipathic amide lipid (A) and component (B) in **a ratio of from 1:1 to 1:30**.

Hoshino et al. had been cited for a disclosure of an external preparation which comprises an amphipathic amide lipid **but fails to disclose the claimed component (B)** nor a

cationic polymer (page 3 of outstanding official action May 15, 2009 and page 4 of advisory action). There is no disclosure of a silicone hair conditioning agent.

Uchiyama et al. describes a conditioning shampoo comprising about 5 to about 50 wt. % of a detersive surfactant, about 0.9 to about 10 wt. % of a fatty compound, about 0.05 to about 20 wt. % of a hair conditioning agent which can be a nonvolatile dispersed silicone conditioning agent, and about 20 to about 94.05 wt. % of water (column 2, lines 23-41). In order to assist with dispersion of the silicone hair conditioning agent, a silicone suspending agent may be added (column 21, lines 48-51). Ethylene glycol stearate is described as a preferred silicone dispersant for suspending the silicone hair conditioning agent (column 21, lines 62-65). There is no disclosure of an amphipathic amide lipid. Thus, Uchiyama et al.'s reason for including ethylene glycol stearate in a conditioning shampoo composition would be to act as **a suspending agent for a silicone hair conditioning agent**.

The two references separately disclose the two components of the claimed composition, but do not suggest the combination of the two in a hair cosmetic composition.

In contrast, the claimed invention is directed to a hair cosmetic composition comprising an amphipathic amide lipid (A) and a component (B) in a ratio of 1:1 to 1:30. The claims recite a ratio of components (A):(B) of 1:1 to 1:30.

It would not have been obvious to include components (A) and (B) in a hair cosmetic composition in a ratio of 1:1 to 1:30 as the cited art **does not disclose any relationship** between the two components.

As noted previously, Uchiyama et al. describe that ethylene glycol stearate is a dispersant for **a silicone hair conditioning agent**. The dermatologic preparation of Hoshino et al. fails to disclose a silicone hair conditioning agent. Thus, there would be no motivation to add the dispersant for a silicone hair conditioning agent of Uchiyama et al. into the dermatologic preparation of Hoshino et al. as suggest in the official action, at an (A):(B) ratio

of 1:1 to 1:30, as Hoshino et al.'s composition does not contain a silicone hair conditioning agent. Where is the motivation to have a ratio of amphipathic amide lipid to dispersant for a silicone hair conditioning agent of 1:1 to 1:30 in a composition which does not contain a silicone hair conditioning agent? There would be no motivation to have a relative ratio of components when the motivation of including a dispersant for a silicone hair conditioning agent is not present. Accordingly, the claimed invention in which the amphipathic amide lipid and component (B) are present in a ratio of 1:1 to 1:30 would not have been obvious.

Patent Claim Language Does Not Provide Motivation To Combine Components

Applicants wish to thank the examiner for the treatise on the term "comprising" and how Moleculon Research corp. v. CBS, Inc teaches that this transitional phrase permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts.

While applicants do not disagree with the basic analysis of U.S. claim interpretation set forth in Moleculon used to interpret a patentees claim language **for the purposes of infringement and validity** the open ended nature of this transitional phrase does not impact the analysis as how one of ordinary skill in the art would interpret the disclosure for purposes of its teachings.

While the examiner has correctly noted that the term "comprising" is open ended and allows for a **claim interpretation** which permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts, such an open ended analysis would make obvious the presence of anything, such as strychnine or the H1N1 virus. Is the examiner suggesting that it would be obvious to formulate the hair conditioning agent of EP '766 with strychnine or the H1N1 virus simply based on the use of the transitional phrase "comprising"? Those of ordinary skill in the art

would not base such a research decision on the legal significance of the transitional claim language used in European patent.

Further, applicants note that EP '766 is the disclosure of **a European patent** such that the interpretation of the claim language would be subject to those of European patent law, not U.S. patent law. Thus, the guidance provided by Moleculon would be moot to the interpretation of the language of a **European** patent document. Did the patentees, in seeking patent protection **in Europe** consider interpretation of U.S. patent case law in choosing the term "comprising"? If the Examiner is qualified to opine as to the meaning of the claim terms of a European patent, applicants would welcome evidence of such legal credentials. Alternatively, applicants would welcome the Examiner's affidavit as to the interpretation of European patent terms. The examiner is reminded that patent claims are interpreted under the issuing jurisdiction which has developed its own juris prudence. As is immediately apparent, application of the laws of claim interpretation to substantive analysis of obviousness can lead to some absurd results.

Bringing the discussion back into focus, there simply is no motivation to use a silicone dispersant in a composition which does not contain a silicone to be dispersed.

No Motivation To Include The Silicone Suspending Agent Of U.S. '705 In The Silicone Devoid Composition Of EP '766

As previously noted the composition of EP '766 fails to disclose a silicone hair conditioning agent. None the less, the office action reasons that the common identity as "oily substances" would lead one of ordinary skill in the art to use the silicone suspending agent of U.S. '705 as a suspension aid for the amphipathic amide lipid of EP '766.

The examiner's citation to XP 002295514 in the Advisory Action and its identification of ethylene glycol distearate as an opacifier is of no moment, as there is no rejection based on this reference.

No Motivation To Relate Content Of The Silicone Suspending Agent Of U.S. '705 To The Content of Amide Lipid of EP '766

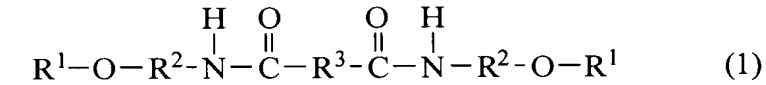
The record clearly reflects that EP 766 does not disclose ethylene glycol disterarate and U.S. '705 fails to disclose an amide lipid. The separate disclosure of components of two separate compositions fails to provide any suggestion to have a ratio of amide lipid to glycol fatty acid ester of 1:1 to 1:30. There is an abundance of hand waving in the reasoning provided in the office action and a paucity of evidence.

An Amphipathic Amide Lipid Is Structurally Different From A Silicone Hair Conditioning Agent

There is no structural similarity between an amphipathic amide lipid and a silicone hair conditioning agent such that suspension of one does not suggest suspension of the other.

The silicone hair conditioning agent of U.S. '705 is non-volatile and preferably has a boiling point of about 250° or higher (column 12, lines 41-47). The agent has a viscosity at 25°C of from 1,000 to about 2,000,000 centistokes (column 12, lines 55-57) and includes structures of polyalkyl siloxanes, polyaryl siloxanes, polyalkylaryl siloxanes, polyether siloxane copolymers and mixtures thereof (column 12, lines 63-66). Thus, the silicone hair conditioning agent is a non-volatile polymeric silicone.

In contrast, the amphipathic amide lipid of EP '766 has a completely different structure of



(1)

The structure has no silicon atoms and does not have a polymeric structure. Due to the stark differences in structure, those of ordinary skill in the art would not be motivated to use the silicone suspending agent of U.S. '705 to suspend the amphipathic amide lipid of EP

'766. The unsubstantiated assertions that the two materials are common as oily substances is not sufficient.

Further, there is no suggestion in EP '766 that an amphipathic amide lipid is in need of suspension assistance by use of a suspending agent.

Nowhere in EP '766 is there a disclosure that the amphipathic amide lipid is in need of suspension stabilization. Nowhere does EP '766 describe the amphipathic amide lipid as in the form of a suspension. There is only a disclosure at paragraph [0020] of forms as w/o and o/w emulsion cosmetics, creams, cosmetic milky lotions, cosmetic lotion, oily cosmetic lipstick, foundation, bath agent skin cleanser, nail treatment and hair cosmetics and that the cosmetic containing the diamide derivative may be formulated into an aqueous solution, ethanol solution, emulsion, suspension, gel, solid, aerosol or powder without limitation [0027]. Thus, there is no suggestion of the need to assist suspension of the amphipathic amide lipid such that there would be no motivation to include the silicone suspending agent of U.S. '705 in the composition of EP '766. Applicants disclosure on page 3, lines 20-21 is irrelevant to the expectation of those of ordinary skill in the art as applicants' specification is not available as prior art against the claimed invention.

A Ratio Of 1:1 to 1:30 Does Not Flow From Overlapping Concentrations

The office action reasons that the content of amphipathic amide lipid of 0.001 to 50 wt. % according to EP '766 when coupled with the disclose content of 0.1 to 10 wt. % of silicone suspending agent used to suspend a silicone hair conditioning agent would meet the claimed range of 5:1 to 1:1,000.

Not withstanding the lack of motivation to even include the silicone suspending agent of U.S. '705 in the silicone lacking composition of EP '766, the newly claimed ratio of 1:1 to 1:30 would not be met. Based on the endpoints of concentrations for the two agents one

could calculate a range of ratios of 500:1 to 1:10,000. Such a broad range fails to make obvious the claimed range of 1:1 to 1:30.

Withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

Moreover, applicants observe an enhancement in hair penetration of the amphipathic amide lipid when combined with component (B). The examiner's attention is again directed to Table 1 on page 29 of applicants' specification which evaluates the hair conditioning performance of the claimed combination of components (A) and (B) as compared with compositions lacking component (B) (comparative example 1) or lacking component (A) (comparative example 2). For the examiner's convenience a portion of the data is reproduced below:

Table 1

(Unit of content is wt.%)

		Examples			Comparative Examples	
		1	2	3	1	2
(A)	Amphipathic amide lipid A	0.5	-	0.5	-	-
	Amphipathic amide lipid B	-	0.1	-	2	-
(B)	Ethylene glycol distearyl ester	2	-	-	-	1
	Distearyl ether	-	2	2	-	-
Others	Sodium polyoxyethylene (2) lauryl ether sulfate	10	10	10	10	10
	Sodium lauryl sulfate	5	5	5	5	5
	Cocoyl monoethanolamide	0.5	0.5	0.5	0.5	0.5
	Cationic hydroxyethylcellulose	0.3	0.3	0.3	0.3	0.3
	Cationic guar gum	0.5	0.5	0.5	0.5	0.5
	50 wt.% aq. NaOH soln/50 wt.% citric acid	q.s. *	q.s. *	q.s. *	q.s. *	q.s. *
	Purified water	Bala-nce	Bala-nce	Bala-nce	Bala-nce	Bala-nce
pH		3.5	3.5	3	3.5	3.5
Buffering capacity (NaOH-gram equivalent/L)		0.02	0.01	0.01	0.01	0.01
Evalu-ation	Resilience and strength of hair	3.1	2.7	3.9	1.8	1.6
	Smoothness of hair	3.8	3.6	3.8	2.1	1.2
	Moist feeling of hair	3.8	3.7	3.8	2.2	1.0
	Storage stability (50°C × 1 month)	A	A	A	C	A

*: amount enough for pH adjustment

Example 1 containing amphipathic amide lipid A and ethylene glycol distearyl ester exhibited high evaluation for hair conditioning performance in terms of resilience and

strength of hair, smoothness of hair and moist feeling of hair plus, no change in appearance upon storage at 50°C for one month.

Example 2 containing amphipathic amide lipid B and distearyl ether exhibited high evaluation for hair conditioning performance in terms of resilience and strength of hair, smoothness of hair and moist feeling of hair plus, no change in appearance upon storage at 50°C for one month.

In contrast, comparative example 1, having amphipathic amide lipid B but no ethylene glycol distearyl ester exhibited lower hair care performance and exhibited separation or gelation upon storage at 50°C for one month. Applicants further note that example 2 and comparative example 1 each contained the same amphipathic amide lipid B, but example 2 which further comprised distearyl ether, but a smaller amount of amphipathic amide lipid B demonstrated enhanced resilience and strength of hair, smoothness of hair and moisture feeling of hair.

Page 7 of the official action asserts applicants' observation of smoothness and moist feeling to be expected as a result of using an amphipathic amide lipid. However, the **degree of enhancement** of smoothness and moist feeling for example 2 with only 0.1 wt.% of amphipathic amide lipid B was far in excess to that of comparative example 1 which contained 20 x the amount of amphipathic amide lipid B, at 2 wt. %. Thus, through the combination of amphipathic amide lipid and component (B), applicants are able to observe an improved hair protecting effect which is not suggested in the cited art of record.

> Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness *In re Chupp* 816, F2d. 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir 1987). M.P.E.P.§§ 2145

Further, contrary to the assertions in the official action that applicants' observation of enhanced dispersion stability for the amphipathic amide lipid is expected, applicants'

observance of enhance dispersion stability is not suggested by the cited art since the silicone suspending agent for a silicone hair conditioning agent would not have been expected to enhance the dispersion stability of an amphipathic amide lipid due to the differences in structure.

The examiner's attention is further directed to page 3 of applicants' specification which states:

> The present **inventors have found** that incorporation of **a compound serving as a pearling agent together with an amphipathic amide lipid** serving as a protecting base in a hair cosmetic composition **improves the dispersion stability** of the amphipathic amide lipid and heightens adsorption of it to the hair to **improve the hair protecting effect** and at the same time, imparts a pleasant feel to hair significantly.

Such statement **must be treated as objectively true**, **unless** the examiner has reasons, based on sound scientific principles, to doubt the objective truth of applicants' specification.

> The burden is on the Patent Office to provide reasons based on scientific principles, to doubt the objective enablement of Applicant's claimed invention. Applicant's disclosure **must be taken as in compliance** with the enabling requirement under 35 USC 112, first paragraph, **unless, there is reason to doubt the objective truth of the statements contained therein**. (*In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)) M.P.E.P. §§2163.04.

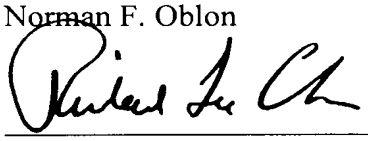
The examiner has provided no basis to doubt the objective truth of applicants disclosure and demonstration such that the claimed demonstration is believed to be commensurate in scope with the claimed invention.

As the cited references fail to provide any motivation to have an amphiphathic amide lipid and component (B) present in a ratio of 1:1 to 1:30, the claimed invention would not have been rendered obvious and withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, L.L.P.
Norman F. Oblon



Richard L. Chinn, Ph.D.
Attorney of Record
Registration No. 34,305

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 07/09)